RD MEDICAL
MANUFACTURING, Inc.
Culebra, P.R.

FEB 1 0 2000

Addendum to 510(k) #K000017

Proposed Devices: PARSET® Secondary Sets, A14001E and A14002E

---

3. 510(k) Summary

Submitted by:
RD Medical Manufacturing, Inc., PO Box 899, Calle Escudero Final, Bo. Fulladosa, Culebra, Puerto Rico, 00775. *Contact*: Carlos A. Rodríguez-García, Ph.D., Product Development Director.

Date of Summary:
February 4, 2000

Trade Name of Proposed Devices:
PARSET® Secondary Administration Set, 30 in.
PARSET® Secondary Administration Set, Luer Lock, 30 in..

Common Name:
Infusion Set

Classification Name:
Intravascular Administration Set (§880.5440).

Predicate Device:
Baxter Secondary Medication, Catalog # 2C1058 (510(k) # K860272).

Description of Proposed Devices:
The proposed secondary administration sets will be used for intravascular administration of fluids and medication via primary administration sets through injection sites on the primary sets. The proposed devices include a needle for connecting the proposed devices to primary sets (via an injection site), and a bag hanger to lower the fluid container of the primary sets (lowering the fluid container decreases the pressure exerted on the fluid container of the primary set and increases the flow rate to the proposed devices compared to the primary set).

Intended Use:
The intended use of the proposed devices is for the intravascular administration of fluids and medication via primary sets through an injection site on the primary sets. Administration of fluids is achieved through gravity from collapsible fluid containers.

Summary of Technological Characteristics of Proposed Devices to Predicate Device
The proposed devices have the same intended use and are composed of the same type of components as the predicate device. The differences between the proposed devices and the predicate device are:

- drops / mL specification: 20 drops / mL for the proposed devices; 10 drops / mL for the predicate device.
- the option of the predicate device to be used with Baxter Flo-Gard® pump set; and
- bag hanger: is composed of metal in the predicate device, compared to plastic in the proposed devices; shorter by approximately $^{7}/_{8}$ in. in the predicate device compared to the hanger in the proposed devices.

Discussion of Non-clinical Tests

Testing of the proposed devices was conducted as per the Recognized Consensus Standards:

- ISO 8536-4: 1987, Infusion equipment for medical use - infusion sets for single use, gravity feed
- ANSI/AAMI/ISO 10993-1: 1997, Evaluation and testing
- ANSI/AAMI/ISO 11607: 1997, Packaging for terminally sterilized products
- ANSI/AAMI/ISO 11137: 1994, Sterilization of health care products- requirements for validation and routine control- radiation sterilization.

The results of the tests conducted for compliance to Recognized Consensus Standards have been provided. All data indicate that the proposed secondary administration sets meet or exceed all functional requirements and therefore supports the suitability of the proposed devices for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2000

Carlos A. Rodriguez-Garcia, Ph.D.
Product Development Director
RD Medical Manufacturing, Incorporated
P.O. Box 899
Culebra, Puerto Rico 00775

Re: K000017
Trade Name: PARSET® Secondary Administration Sets
Regulatory Class: II
Product Code: FPA
Dated: December 27, 1999
Received: January 3, 2000

Dear Dr. Rodriguez-Garcia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PROPOSED DEVICES: PARSET(r) SECONDARY SETS, A14001E AND A14002E

Indications For Use

510(k) Number (if known)_____

Device Name: PARSET SECONDARY SETS

Indications For Use:

THE DEVICES ARE USED TO SUPPLY MEDICATION AND FLUIDS INTRAVASCULARLY THROUGH A NEEDLE INSERTED INTO THE INJECTION SITE OF A PRIMARY ADMINISTRATION SET.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K00017